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### <u>REMARKS</u>

## Status of the Claims

Claims 1-16 have been cancelled without prejudice or disclaimer and rewritten in proper U.S. format as new claims 17-33. No new matter is introduced by new claims 17-33, as each of these claims finds full support in the application as originally filed, in particular, in original claims 1-16. Claims 25-27, corresponding to original claims 9-11, have been withdrawn from consideration by the Examiner as being drawn to a non-elected invention. Accordingly, claims 17-24 and 28-33 corresponding to original claims 1-8 and 12-16 are pending in this application.

# II. Restriction Requirement

Applicants' original claims 1-16, corresponding to new claims 17-33, are subject to a restriction requirement under 35 U.S.C. § 121. See pages 2-3 of the Office Action dated March 27, 2001. The Examiner has grouped the claims as follows:

Group I: Claims 17-24 and 32-33 (corresponding to original claims 1-8 and 16);

Group II: Claims 25-27 (corresponding to original claims 9-11); and

Group III: Claims 28-33 (corresponding to original claims 12-16).

Applicants respectfully traverse this requirement. A restriction requirement is proper only when the Examiner satisfies two criteria: (1) the inventions subject to restriction are either independent or distinct, and (2) simultaneous examination of the inventions would result in a serious burden on the Examiner. M.P.E.P. § 803.

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The Examiner, in the present case, has not satisfied either of these two requirements.

The criteria for a satisfactory showing of distinctness, for inventions having the combination/subcombination relationship, is set forth in M.P.E.P. § 806.05(c). This section provides that, when it cannot be shown that "a combination as claimed:

(A) does not require the particulars of the subcombination as claimed for patentability ... and (B) the subcombination can be shown to have utility either by itself or in other and different relations," such inventions are not distinct. M.P.E.P. § 806.05(c). The Examiner states that "[i]n the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because." See page 1, lines 9-11 of the Office Action dated March 27, 2001. By not providing any reasoning/proof after the term "because" in the Examiner's statement, the Examiner has failed to provide the requisite proof to support this prong of the test for distinctness. Accordingly, Applicants respectfully submit that because the Examiner has not provided any proof to support the first part of this test, the Examiner has not shown that Applicants' combination and subcombination are distinct.

In addition to showing distinctness, the test for a proper restriction . requirement directs the Examiner to show that a *prima facie* case of a serious burden exists. M.P.E.P. § 803. The Examiner "must show by appropriate explanation one of the following: (A) [s]eparate classification ... separate status in the art ... [or] a different field of search." M.P.E.P. § 808.02 (emphasis supplied).

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As not even one of these showings has been made, the Examiner has failed to establish that a serious burden exists.

Examiner to provide an appropriate explanation of why a serious burden exists,
Applicants herewith provide support for the proposition that a serious burden does
not exist. No serious burden exists for at least the reason that there is evidence of
Applicants' subject matter having the same status/classification in the art, thus the
respective searches would overlap.

First, Applicants submit that, in the pharmaceutical art, at least claims directed to a compound and claims directed to a composition comprising such a compound have traditionally been examined together in the same application. This fact is demonstrated by U.S. Patent No. 5,726,151, cited in the Information Disclosure Statement ("IDS") filed April 27, 2000. Additionally, in the pharmaceutical art, claims directed to a compound, claims directed to a composition comprising such a compound, and claims directed to methods of preparing such compounds have traditionally been examined together as well. For example, U.S. Patent No. 5,637,565, which is also cited in the IDS mentioned above, encompasses all three types of claims.

Second, Applicants submit that a search of the subject matter of Group II and Group III, in addition to the subject matter of Group I, would not present a serious burden to the Examiner. In particular, the search for the subject matter of Group III would include the subject matter of Group I. Furthermore, Applicants submit that a

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search of the subject matter of Group II and Group III would appear to nearly overlap in scope with the search of the subject matter of Group I, because all of the claims within those groups recite a group A streptogramin derivative of formula (I).

Accordingly, because the Examiner has failed to present a prima facie case that a serious burden exists, Applicants respectfully traverse the restriction requirement. However, to be fully responsive to the restriction requirement, Applicants elect, with traverse, the subject matter of Group I, claims 17-24, and further request that in view of the above remarks at least the subject matter of Group III, claims 28-33, be joined with the subject matter of Group I for prosecution on the merits. Applicants do not make any statement regarding the obviousness of one group relative to any other, nor should one be inferred. Applicants merely assert that the search of all the pending claims would not be unduly burdensome. Therefore, the restriction requirement should be withdrawn, or at least modified as requested above.

### **Election Requirement** 111.

Under 35 U.S.C. § 121, the Examiner has required Applicants to elect, from Group I above, a disclosed species for prosecution on the merits and to elect a second species for prosecution on the merits from Group III above. See page 3 of the present Office Action. Applicants respectfully traverse this election of species requirement. However, to be fully responsive to the Examiner's requirement, Applicants, with traverse, elect (16R)-16-dimethylamino-16-deoxopristinamycin II<sub>A</sub>

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(Specification, page 13) for the species of Group I and pristinamycin  $I_{\textrm{B}}$ (Specification, page 8) for the species of Group III.

Applicants traverse on the ground that it would not be unduly burdensome for the Examiner to conduct a search for all the claimed compounds, as it is likely that art encompassing the elected species would also encompass the other claimed species. Applicants do not make any statement regarding the obviousness of one species relative to any other, nor should one be inferred. Applicants merely assert that a search of all the claimed species would not be unduly burdensome.

Accordingly, Applicants respectfully request that all of the claimed species be examined in this application. If the Examiner chooses to maintain the election requirement, Applicants expect the Examiner, if the elected species are found allowable, to continue to examine the full scope of the elected subject matter to the extent necessary to determine the patentability thereof, and then to extend the search to a reasonable number of the non-elected species, as is the Examiner's duty according to M.P.E.P. § 803.02 and 35 U.S.C. § 121. In any case, the election of species requirement should be withdrawn in view of the foregoing remarks.

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#### IV. Conclusion

In view of the foregoing remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: May 29, 2001

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